REMARKS

Reconsideration and withdrawal of the rejections to the application are respectfully requested in view of the remarks herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 96-116 and 127-129 are currently pending. New claims 127-129 have been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is respectfully submitted that the claims, as originally presented and as herein presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The claims presented herein, are not amended for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these claims are amended simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE ART REJECTIONS ARE OVERCOME

Claims 96-97 and 99-116 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Quelle *et al.* with evidence provided by Dorland's Illustrated Medical Dictionary and claims 96-116 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Quelle *et al.* with evidence provided by Dorland's Illustrated Medical Dictionary. The rejections are respectfully traversed and will be addressed collectively.

The July 25, 2006 Advisor Action stated that Quelle *et al.* "teaches a similar product prepared in the similar manner as claimed and having the same range of activity (i.e., 200,000 U/mg to 500,000 U/mg) determined in vitro and a little activity, if any in vivo". Advisory Action at 2.

Initially, Applicants maintain that Quelle *et al.* fails to teach an erythropoietin purified to 95% or greater, having *in vivo* activity. Indeed, Quelle *et al.* even speculates as to the absence of *in vivo* activity having been the result of the "relatively limited level of glycosylation" which results in "absence of sialic acid" (Quelle et al. page 656, column 1, lines 22-26). Furthermore, Applicants respectfully assert that the Examiner has misread Quelle *et al.* as to the *in vitro*

activity shown by Quelle *et al.* such that Quelle *et al.* additionally fails to teach an erythropoietin purified to 95% or greater, having *in vitro* activity of at least 200,000 U/mg or of about 500,000 U/mg.

Initially, it is respectfully pointed out that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). It is also well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The presently pending claims relate to a substantially pure, recombinant glycosylated erythropoietin, produced by a baculovirus expression system in cultured insect cells, wherein said erythropoietin has relative homogeneity or is purified to 95% or greater and said erythropoietin stimulates erythropoiesis and has an *in vivo* activity and an activity of at least 200,000 U/mg or of about 500,000 U/mg.

Applying the law to the instant facts, it is respectfully submitted that the instant invention is not anticipated or made obvious by Quelle, *inter alia*, because Quelle does not contain a teaching of all of the elements of the instant claims. And, it is respectfully submitted that the instant invention is not rendered obvious by Quelle, as Quelle does not provide a teaching or suggestion of all of the elements of the instant claims, *inter alia.*

The December 30, 2005 Office Action states that Quelle *et al.* teaches "a glycosylated, >99% pure, recombinant human erythropoietin produced by a baculovirus expression system, said expression system cultured in an insect cell, wherein said erythropoietin has an activity of

200,000 U/mg protein," and cites to page 652, column 1, lines 6-25 and column 2, lines 6-13 for support. Office Action at 3. The Office Action also states that "Quelle *et al.* teach a similar product prepared in the same manner and having same range of activity (i.e., 200,000 U/mg to 500,000 U/mg)." Office Action at 4. Applicants respectfully disagree with these assertions.

Quelle *et al.* utilizes the [3H] thymidine test to determine the biologic activity of various preparations of erythropoietin (see page 1, column 2, last paragraph). The results of that test are shown in the last column of Table 1 on page 653, which indicates that the various preparations had specific activities of 230 U/mg, 10,000 U/mg, 180,000 U/mg or 200,000 U/mg. Nowhere in Table 1, or anywhere else in Quelle *et al.*, is a **specific activity of 500,000 U/mg** provided.

Indeed, the only place in the entire article that the number 500,000 is found is in reference to concentrations, not specific activities. That is, Quelle *et al.* discusses **concentrations** of 500,000 **U/L**, not **specific activities** of 500,000 **U/mg**. Indeed, the number 500,000 only appears at page 653, column 1, lines 35 and 45, and in Table 1, second column, where it is indicated that a **concentration** of secreted erythropoietin of 500,000 U/L was obtained and processed.

Consequently, the Office Action's assertion that Quelle *et al.* describes "a similar product prepared in the same manner and having same range of activity (i.e., 200,000 U/mg to 500,000 U/mg)" is clearly **in error** as Quelle *et al.* teaches only an erythropoietin having **at most** an activity of 200,000 U/mg. There is no teaching or suggestion in Quelle *et al.* of an erythropoietin having an activity of more than 200,000 U/mg, such that Quelle *et al.* cannot be asserted to teach or suggest an erythropoietin purified to 95% or greater, having *in vitro* activity of **at least 200,000 U/mg** or of **about 500,000 U/mg**.

Indeed, the phrase "at least 200,000 U/mg" indicates that 200,000 U/mg is the **minimum** specific activity of the claimed erythropoietin, which is in direct contrast to Quelle *et al.* which teaches a **maximum** specific activity of 200,000 U/mg. Therefore, Quelle *et al.* cannot be considered to teach or suggest an erythropoietin having an activity of **at least** 200,000 U/mg as Quelle *et al.*, **does not** provide an erythropoietin having an activity of **over** 200,000 U/mg, and certainly does not teach or suggest an erythropoietin having an activity of about 500,000 U/mg.

Therefore, because Quelle *et al.* does not contain all the elements of the presently claimed invention, and because Quelle *et al.*, either alone or in combination with any other reference, does not provide any teaching, suggestion, motivation, or incentive to modify to allow one of

skill in the art to arrive at the present invention, it is respectfully requested that the rejections under 35 U.S.C. §§ 102(b) and 103(a) be reconsidered and withdrawn.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

The remarks herein place the application in condition for allowance. An early and favorable consideration of the application on the merits, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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